U.S. Application No.: 09\863,316

Att rney Docket No.: GOT-0011

"A method of inhibiting skin cancer in a mammal, comprising the step of

administering to the mammal a composition comprised of sericin."

The Examiner first objected to the claims because the body of the claim (starting with the

phrase "the step of ...") should indicate with particularity the subset of mammals to which that

the sericin is being administered. In response, the body of the claim is amended to read:

"... administering to a mammal in need of treatment for inhibition of skin

cancer a composition ...."

The present invention is primarily directed to use by patients that need to inhibit or

prevent skin cancer, and not necessarily to patients suffering from skin cancer. In making the

above objections to the claims, the Examiner noted that "[c]laims not specifying the subset of

patients to be treated in this manner are generally viewed as being anticipated by any prior art

method using a given agent since they read on administration to the general population and not a

specified subset requiring treatment." Therefore, it is hoped that the Examiner will withdraw the

rejections based on the prior art in light of the present amendment, because as discussed below,

the prior art cited by the Examiner fails to mention patients in need of treatment for inhibition of

skin cancer.

The Examiner also objected to claims 7 to 8, and 11 to 12, suggesting that the claims be

amended to be placed in Markush claim language. The present amendment complies with this

suggestion.

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Claims 5, 7 to 9, and 11 to 12 are rejected under 35 U.S.C. § 102(a) as being anticipated by the previously cited U.S. Patent No. 6,165,982 ("Yamada"). The Examiner concedes that Yamada fails to teach the use of sericin to inhibit skin cancer. However, the Examiner asserts that Yamada teaches that sericin is medicinally useful as an antioxidant (abstract) and that naturally-derived antioxidants are useful in countering the oxidative effects of lipid peroxides which are known cancer causing agents (col. 1, lines 15 to 33). The Examiner's position is that when preventing cancer by administering sericin for the purpose of inhibiting the ill effects of lipid peroxides, an inherent result would include the inhibition of skin cancer. Thus, the Examiner asserts that Yamada inherently anticipates claims 5, 7 to 9, and 11 to 12.

The Examiner also rejects all of the claims under 35 U.S.C. § 103(a) as being obvious over Yamada, for essentially the same reasons set forth above.

The above amendment renders the claims patentable over Yamada. Even though Yamada teaches that sericin can be used to counter the ill effects of lipid peroxides, which effects can include cancer, there are myriad types of cancer with very different preventative treatments for each. Further, when speaking of cancer generally it is understood that most anything that improves the overall health of a patient, i.e., vitamins, exercise, healthy diet, low stress, etc. would be beneficial in terms of combating the possibility of the onset of some sort of cancer.

Skin cancer is a very particular type of cancer for which specific therapies are widely published due to the wide spread nature of the cancer throughout much of the earth's population. Consequently, documents that mention cancer generally are just slightly more pertinent to the art of inhibiting skin cancer than documents that mention another disease. The mere suggestion of the use of sericin as a cancer preventative agent due to its antioxidant properties does not suggest

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to a person skilled in the particular art of treating patients in need of inhibiting skin cancer that

sericin would be beneficial for such a relatively narrow group of patients. In light of the above, it

is respectfully requested that the rejections of claims 5 to 12 be withdrawn.

If the Examiner has any comments or suggestions that could place this application in even

better form, the Examiner is requested to telephone the undersigned attorney at the below-listed

number.

Respectfully submitted,

DATE: February 20, 2003

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## **APPENDIX** Amendments to the Claims

- U.S. Applicati n N .: 09\863, 300
  Attorney Docket Na.: GOX-0011 5. (amended) A method of inhibiting skin cancer in a mammal, comprising the step of administering to the mammal in need of treatment for inhibition of skin cancer a composition comprised of sericin.
- 7. (amended) The method of Claim 5, where said administering step is comprised of administering the composition by a means selected from the group consisting of oral, intraperitoneal, intravenous, [or] and topical means.
- 8. (amended) The method of Claim 6, where said administering step is comprised of administering the composition by a means selected from the group consisting of oral, intraperitoneal, intravenous, [or] and topical means.
- 9. (amended) A method of inhibiting skin cancer in a mammal, comprising the step of administering to the mammal in need of treatment for inhibition of skin cancer a composition comprised of a hydrolysis product of sericin.
- 11. (amended) The method of Claim 9, where said administering step is comprised of administering the composition by a means selected from the group consisting of oral, intraperitoneal, intravenous, [or] and topical means.
- 12. (amended) The method of Claim 10, where said administering step is comprised of administering the composition by a means selected from the group consisting of oral, intraperitoneal, intravenous, [or] and topical means.